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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,199	Applicant(s) KRONZON, ITZHAK	
	Examiner CHRISTOPHER A. FLORY	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10-15 and 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 21 December 2007 have been fully considered but they are not persuasive. Claims 1-5, 7, 8, 10-15 and 17-26 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claims 1-5, 7, 8, 10, 12-15 and 17-26 stand rejected under 35 U.S.C. 102(e) as anticipated by Friedman'167 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Friedman'167 in view of Atlee'116, or in view of Melnikoff'549 or in view of Venrooij'867. Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman'167, or in the alternative is unpatentable over Friedman'167 in view of Shadduck'419.
2. Regarding Applicant's arguments against the rejection of the claims under 35 U.S.C. §112, first paragraph, it is noted that it is Applicant's own arguments presented 21 December 2007 which are used to establish that a disclosure of c-shaped electrodes or showing in a figure an opening within a ring-like structure is not sufficient grounds to establish support for a non-annular structure. In fact, the Applicant argued the contrary--that these things in fact are an explicit disclosure of an annular structure--in their Arguments against the Friedman'167 reference. One cannot selectively establish that within one's own disclosure such statements are conclusive evidence of a non-annular structure when one has previously argued and herein maintains the argument that the exact same disclosure or showing in the figures of the prior art establishes evidence of

an annular structure. Therefore, the rejection under §112, first paragraph is considered proper based on Applicant's own arguments and is herein maintained.

3. Applicant once again argues that the electrodes of Friedman'167 are annular. In support of this, Applicant offers the self-defeating argument that a ring need not be contiguous or unbroken in nature to constitute an annular shape. However, this is contradictory to Applicant's own invention, e.g. in Fig. 4a, which can also be considered annular by this broad interpretation of the word. Even so, the opening presented in Friedman'167 as shown in Fig. 5 presents a reasonable grounds to suggest that the sizing of the opening and directionality of stimulation thereby delivered would be an obvious range subject to routine experimentation by one skilled in the art.

4. Applicant also argues that the contacts 25 as shown in Friedman cannot be used as electrodes because Friedman'167 does not specifically state them to be electrodes (See page 3, paragraph 2 and page 7, paragraph 1). Examiner maintains that the contacts are capable of functioning as electrical contacts to generate electrical stimulation, the instant claims being directed to an apparatus, such that the intended use of the instant claims need not be explicitly recited in the rejecting reference wherein the recited structure is capable of performing that function.

5. Applicant argues that it would not have been obvious to combine Friedman'167 with a non-annular electrode as recited in the supporting references because Friedman'167 does not specifically teach the use of a non-annular electrode. It is noted that the motivation to combine the references can substantially or entirely be found in the supporting references (explained herein above) to properly reject a claim under 35

U.S.C. §103(a), and is in the very nature of that rejection necessary since it is being acknowledged that the primary reference is lacking said rejectable claim limitation. In this case, each of the supporting references provided provides proper motivation to combine as explained in the paragraphs above and further explained immediately below.

6. Regarding applicant's arguments directed towards the Atlee'116 reference (see page 5, paragraph 1), the same reasoning as presented above applies. Additionally, Applicant cannot merely select one of a possible number of embodiments to refute the applicability of a reference. In this instance, the embodiments shown in e.g. Figs 10d and 11 are clearly showing non-annular electrodes. Additionally, Atlee'116 specifically teaches that the non-annular electrodes can be embedded in column 6, lines 21-29 and column 8, lines 8-24.

7. Regarding applicant's arguments towards the Melnikoff'549 reference, it is again noted that Applicant cannot selectively single out only one of the presented embodiments to refute the applicability of the reference as a whole. Melnikoff'549 clearly discloses that several embodiments exist, one or several of which include the base structure 52 having a non-conductive material or configuration, which clearly establishes electrode dome 50 to be an electrode of non-annular shape (column 6, lines 21-25; column 8, lines 1-9 and 22-37). Further, Melnikoff'549 explicitly and directly teaches that the electrode can be embedded in column 7, lines 25-65.

8. Applicant again argues that it would not have been obvious for one of ordinary skill in the art to modify Friedman'167 with Venrooij'867 because Venrooij'867 discloses

brain stimulation rather than cardiac stimulation. However, it is once again maintained that Venrooij'867 teaches the desired benefit of directionally selective stimulation to stimulate desired structures while avoiding stimulation of undesired structures and similarly to Friedman'167 innervates nerve tissue structures. Further, the windowed structure taught in Venrooij'867 is non-annular in nature and provides the intended use function of the instant claims. Further, it is specifically noted that Venrooij'867 identically discloses embedded electrode structures in column 5, lines 23-67; column 6, line 62 through column 7, line 11; and column 15, lines 32-45.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-5, 7, 8, 10-15 and 17-26 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has amended the independent claims 1, 14 and 20 to include the limitation of a "non-annular" electrode, and non-annular is nowhere supported in the disclosure of the invention. Particularly in the case of the negative or alternative, the limitation must be explicitly set forth in the Specification. In this case, no reference is made to "annular," "ring-like," "circular," or their negative

alternatives. Furthermore, it is per Applicant's own arguments of 21 December 2007, that the Applicant's own invention can be considered annular in nature, e.g. as shown in Fig. 4a, since the electrode is substantially ring-like in shape, and Applicant is suggesting that a shape need not be a contiguous or uninterrupted ring structure to constitute an annular electrode. Therefore, the disclosure language relating to being c-shaped and the electrodes as shown in Figures 3b and 3c are not sufficient to establish the concept of non-annular per Applicant's own arguments.

Claim Rejections - 35 USC § 102/103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-5, 7, 8, 10, 12-15 and 17-26 stand rejected under 35 U.S.C. 102(e) as anticipated by Friedman (US Patent Publication 2003/0097167, hereinafter referred to as Friedman'167) or, in the alternative, under 35 U.S.C. 103(a) as obvious over

Friedman'167 in view of Atlee, III (US 6,855,116, hereinafter Atlee'116), or in view of Melnikoff et al. (US 6,266,549, hereinafter Melnikoff'549) or in view of Van Venrooij et al. (US 7,212,867, hereinafter Venrooij'867).

Regarding claims 1-5, 10, 14 and 19, Friedman'167 discloses a medical apparatus used to treat cardiac arrhythmia comprising a flexible probe for accessing a patient's esophagus via the mouth with a proximal end which remains outside the patient and a distal end within the esophagus (TITLE; ABSTRACT; paragraphs [7], [10] and [32]); an echocardiography transducer coupled to the distal end at a predetermined location within the esophagus relative to the heart to perform transesophageal echocardiography (Fig. 1 TEE probe 3; paragraphs [6], [10] and [32]); and a plurality of electrodes spaced along a longitudinal axis of the probe included in the sheath (Fig. 2, electrodes 26; Fig. 3, leads 1-8) each coupled to a wire lead extending along the probe to a power source (paragraphs [9], [28] and [29]) for delivering a cardioversion or defibrillation current via the esophagus (paragraphs [15]-[17] and [36]-[38]).

Regarding claims 24 and 25, and further regarding claims 1, 14 and 20, Friedman'167 clearly shows in Figure 5 that the electrode assembly is C-shaped and non-annular. Alternatively, it is noted that the electrical contacts embedded within the sheath are functional as electrodes in an operative position themselves, and clearly define a non-annular shape with a length no more than half of the circumference of the probe which is embedded in the sheath, which also means an opening of at least 110 degrees. Still further in the alternative, Venrooij'867 describes non-annular C-shaped electrodes for directional stimulation and recording to improve localization of signals

Art Unit: 3762

(title; abstract; column 15, line 39; Figures 3, 4, 6, 18). Shadduck'419 teaches non-annular electrodes (Figs. 5A-F) to be applied to the lower esophageal sphincter to induce injury healing response (abstract; column 9, lines 6-56). Atlee'116 shows an esophageal probe with C-shaped non-annular electrodes for providing cardiac pacing and oximetry (title; abstract; Figure 10 and related paragraphs). Melnikoff'549 teaches non-annular electrodes that are configured to be placed in the esophagus to generate or receive electrical signals indicative of the cardiac functions of the patient (abstract; Figs. 6, 11, 15, 17). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Friedman'167 with the non-annular electrodes as taught by any one of these references to provide Friedman'167 with the respective advantages described in this paragraph as taught by Venrooij'867, Shadduck'419, Atlee'116 and Melnikoff'549.

Further regarding claims 1, 14 and 20, it is noted that each of Atlee'116, Melnikoff'549 and Venrooij'867 discloses the limitation of the non-annular electrodes being embedded within the sheath. Atlee'116 discloses this in column 6, lines 21-29 and column 8, lines 8-24. Melnikoff'549 discloses embedded electrodes in column 7, lines 25-65. Venrooij'867 specifically discloses embedded c-shaped electrodes in column 5, lines 23-67; column 6, line 62 through column 7, line 11; and column 15, lines 32-45, stating that this allows for formation of specific electrode surfaces without windowing techniques, as well as allowing the electrodes to be flush or protrude relative to the lead surface as desired.

Further regarding claims 24 and 25, given the interpretation of Friedman'167 that the electrical contacts within the sheath are functional electrodes, Friedman'167 clearly shows electrodes with a length no more than half of the circumference of the probe and an opening of at least 110 degrees. Alternatively, regarding the non-annular electrode ring shown in Fig. 5, although it is not expressly disclosed that the length be no more than half the circumference, it would have been obvious to one having ordinary skill in the art at the time of the invention to construct the electrode with such a length or angle of opening since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode as taught by Friedman'167, because it provides a means of providing electrical stimulation to the esophagus as well as a means of snapping/clamping the electrode to the probe body and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Friedman'167. Still further in the alternative, each of Venrooij'867, Shaddock'419, Atlee'116 and Melnikoff'549 clearly shows a non-annular electrode with a circumferential length no more than half that of the circumference of the probe, and with an opening of at least 110 degrees. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Friedman'167 with the electrodes as shown in these references, because

Applicant has not disclosed that a length of less than half the circumference or an opening angle of at least 110 degrees provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrodes as disclosed in Friedman'167, because it provides a means of providing electrical stimulation to the esophagus as well as a means of snapping/clamping the electrode to the probe body and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application.

Therefore, it would have been an obvious matter of design choice to modify the system of Friedman'167 to obtain the invention as specified in the claim(s).

Regarding claims 7, 17, 18 and 26, and further regarding claims 1 and 14, Friedman'167 discloses the electrodes mounted on or within a flexible sheath which is sized to be received over a distal portion of the probe and fixed thereon at a predetermined location relative to the echocardiography transducer (paragraphs [6], [7], [10]-[12] and [32]), the sheath being made of a biocompatible material (paragraph [32] discloses a sheath made of silicone) wherein the sheath/electrode is selectively mountable on and removable from the scope portion (paragraphs [11], [12] and [32]). It is noted that the electrical contacts within the sheath are functional as electrodes in an operative position themselves, and also that the act of clamping the electrode rings to the sheath can be reasonably interpreted to mean a sheath including an electrode.

Regarding claim 8, Friedman'167 discloses that the sheath can also be permanently bonded to the probe (paragraphs [34] and [35]).

Regarding claims 12 and 13, Friedman'167 discloses the electrode having a length of 7-10mm along an axial direction of the probe and being separated from a second electrode by a distance of 5-8mm (Fig. 3).

Regarding claim 15, Friedman'167 discloses an electrode assembly that is one of a single use assembly and a multiple use assembly, in that a single use assembly is defined identically to a removable and selectively mountable assembly, and a multiple use assembly is synonymous with a permanently bonded assembly as discussed with regards to claim 6, 8 and 9.

Regarding claim 20, Friedman'167 discloses a method of treating a heart of a patient comprising the steps of inserting a flexible echocardiography probe into the patient's esophagus, performing an echocardiography to analyze the condition of the heart, and applying electric current to the at least one cardioversion electrode to supply a current to the heart (paragraphs [13]-[17]).

Regarding claim 21, Friedman'167 discloses performing an additional echocardiography immediately after the cardioversion using the echocardiography transducer (paragraph [18]).

Regarding claims 22 and 23, Friedman'167 discloses coupling the electrode sheath to the probe prior to inserting the device into the esophagus and disposing of the sheath after completing the procedure (paragraphs [6], [7], [10], [11], [12], [32] and [33]).

14. Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman'167, or in the alternative is unpatentable over Friedman'167 in view of Shadduck'419.

Regarding claim 11, Friedman'167 discloses the invention substantially as claimed but does not expressly disclose that the electrode is formed of a titanium foil. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system and method as taught by Friedman'167 with a titanium foil electrode, since it is well known in the art that titanium is a good material for electrode construction due to its relatively low cost, durability, biocompatibility, and good electrical conduction properties. Alternatively, Shadduck'419 teaches electrodes made of titanium, as titanium is a suitable conductive material which is adapted to deliver RF energy to soft tissue of the esophageal lumen without ablating and necrosing surface tissue to a significant degree (column 9, lines 57-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Friedman'167 with the titanium electrodes as taught by Shadduck'419 to provide Friedman'167 with the same advantage of stimulating the esophageal lumen without ablating and necrosing the tissue.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/
23 October 2008

/George Manuel/
Primary Examiner